

29.ocr
SUMMARY OF
NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING
APRIL 18, 2002

This NRC/DOE Quarterly Quality Assurance Meeting was held on April 18, 2002 in Las Vegas, NV with video and audio connections to the NRC office in Rockville, MD, the DOE offices in the Forrestal Building, the Center for Nuclear Waste Regulatory Analyses (CNWRA or the Center) in San Antonio, TX and the Region IV NRC offices. A copy of the agenda is attached (Enclosure 1). A list of attendees is on Enclosure 2. The meeting convened with opening remarks from J. Russell Dyer (DOE). Dr. Dyer's opening remarks are included immediately following the summary of Dr. Chu's remarks.

Summary of Dr. Margaret Chu's Remarks

In her opening remarks, Dr. Margaret S. Y. Chu, Director of DOE's Office of Civilian Radioactive Waste Management (OCRWM), stated her belief that the program is very important to the nation and its security. She believes that quality assurance (QA) is critical to assuring the scientific integrity of the program, and she intends to assure that the QA program is implemented in a manner that will support a successful license application. She emphasized her belief that OCRWM's QA program should:

- Strike the right balance between process and objective;
- Not only identify problems but properly focus on effective corrective actions; and
- Be proactive, not just a reaction to audits or CARs.

She has assigned Gene Runkle of her staff to assist the Yucca Mountain Site Characterization Office in achieving timely and continuous improvements in the QA process.

With regard to selecting a new Director of the Office of Quality Assurance, Dr. Chu indicated that she understands the urgency associated with filling this position and will do so deliberately to assure the right selection. She further indicated that she

expects to interact

with the NRC frequently and actively encourages feedback from the NRC.

The NRC indicated that they were gratified and encouraged by Dr. Chu's understanding of the

importance of management involvement in solving the problems in DOE's QA program.

Dr. Russell Dyer's Opening Remarks

Dr. Dyer stated that the Yucca Mountain Site Characterization Office (YMSCO) is completely on board with Dr. Chu's approach; her involvement and support is key to the project's success.

Both the BSC General Manager (Mr. Ken Hess) and the YMSCO Project Manager (Dr. Dyer) have substantially increased their personal involvement in the development of the OCRWM

-1-

Management Improvement Initiatives (OMII) and will continue personal oversight of the

implementation of the CAR and OMII actions.

YMSCO and BSC management has taken a far more aggressive approach to the problems

than in the past;

OMII is the DOE plan for bringing the Project's culture to a level needed to support

licensed activities;

OMII has been given new leadership and a substantial infusion of resources by DOE,

BSC, the National Laboratories and USGS;

DOE and BSC are re-evaluating the actions in the OMII and are significantly increasing

the detail and, in some cases, the comprehensiveness of the planned actions;

The Project is focusing the actions for the Software and Modeling CARs' root causes to

significantly improve DOE's ability to prevent recurrence;

The OMII will be prepared, issued and administered under the DOE QA program

procedures;

The CAR corrective actions will be addressed via Procedure AP 16.1 Q "Ma

management
of

Conditions Adverse to Quality" and also tracked in OMII;
 • OMII will contain all action plans;
 • Performance metrics will be established and individuals assigned actions will be held accountable. DOE will provide the NRC with their plans for self assessments and QA oversight of the OMII by both DOE and BSC;
 • The results of the performance measures, self assessments and results of QA oversight will be used to identify necessary course changes in our program.

DOE has also chartered a joint DOE and BSC senior management team to conduct a lessons learned evaluation of the past problems in approaching CAR root causes and OMII development.
 • Their objective is to identify and implement lessons learned in the DOE QA Program.
 • To date, they have identified a need to conduct a CAR/Root Cause conflict resolution meeting and the necessity to amend the CAR 001 Response.

Dr. Dyer stated that he would keep the NRC informed as that effort progresses.

Dr. Dyer indicated that DOE has an extensive set of performance metrics which will be provided to the NRC staff monthly. In many cases, the metrics appear to show positive performance; for example, the number of open quality deficiencies and their average age is declining, indicating that successful implementation of corrective actions.

However, he indicated that the statistic cannot be taken by itself, i.e. it does not tell it all:
 • the total number of newly identified deficiencies has decreased over several months as has the percentage of new deficiencies issued by the BSC and DOE line organizations
 • the number of deficiencies open for more than 100 days is increasing

Dr. Dyer indicated that he, Mr. Hess and the leadership team are more directly focusing on these and the other quality metrics than previously.

The OMII addresses improving YMP's self critical attitudes and the need to improve the

ability for the line to identify and address conditions adverse to quality.

The OMII
Leadership

Team (including the YMSCO Director, the BSC General Manager, and their senior staff) is

meeting regularly to review progress and drive action. To improve management of the

program, the YMP Deputy Project Manager has been designated as the "Project Corrective

Action Coordinator." Further:

- BSC, the National Laboratories, USGS, and the DOE Office of Environmental

Management are being directed to identify a responsible Point of Contact to interface with

Dr. Dyer's organization and assist in the oversight and resolution of corrective action

issues in their areas under the cognizance of the Corrective Action Coordinator;

- This responsibility includes evaluating performance metrics and ensuring that appropriate

actions are taken in response to that data;

- This function will also assure that follow up actions such as self assessments to ensure that

DOE corrective actions are effective.

Dr. Dyer noted that his opening remarks were more extensive than they have been in the past,

reflecting the personal involvement and conviction of YMP senior management in improving

performance. DOE intends to regularly update the NRC on status and results.

quality Assurance Program Status (by Mr. Ram Murthy Acting Director OOA) - included as Enclosure 3

Primary topics discussed were the status of the QA organization, Corrective Action Report

status, trending results/emerging issues and the Quality Assurance Requirements

Document

(QARD) revision.

The acceptance of the modeling CAR referred to in the presentation is, in fact, a modified

response. Both CARs are being revisited to assure that there are appropriate and effective

corrective actions. The NRC asked questions regarding the timing of issuing the Lessons

Learned on these (and previous) CARs. The response is that completion of the Lessons

Learned is fairly close, but that it is more important to get it done correctly than to issue it

immediately.

Revision 12 to QARD is planned to incorporate the increased BSC QA responsibility. The

NRC asked if the revision will be in place prior to giving BSC audit responsibility. DOE

responded that this was the plan, but it was possible that the transition could take place

prior

to issuing Rev. 12 (although this would not reflect any reduction in QA commitments).

Current timing for issuing Rev. 12 of the QARD is approximately six to eight weeks from

the

date of the meeting.

There was discussion of the planned revision to the QARD' to appropriately address the

YMRP. NRC cautioned that the YMRP is a draft document and will not be finalized until

after NRC obtains and evaluates public comments on it. Mr. Murthy acknowledged and

stated

1 ~ is currently anticipated that this Will be Revision 13 to the QARD.

-3-

that the QARD revision addressing the YMRP will be issued only after the final

YMRP is

issued and will take account of the changes as a result of the public comments. There was

some discussion of what review criteria and/or comparison documents were being used for

comparison with the YMRP. Ms. April Gil (DOE) indicated that licensing precedence from

the commercial industry should be considered as a principal criteria. Mr. Stephen

Cereghino

(BSC) indicated that, to some extent, the Standard Review Plan (NUREG-0800)

for power

reactors was being used to support their review of the YMRP. Mr. Robert Lat
ta (Onsite

Representative, NRC) indicated that NUREG-0800 was not specifically applica
ble to YMP.

Mr. Cereghino responded that comparable portions of NUREG-0800, particularl
y as they

applied to similar types of systems (especially fuel handling, for example
) were being used

for

review.

OCRWM Management Improvement Initiatives (presented by Mr. Joseph Ziegler)

-

Enclosure 4)

The primary points of Mr. Ziegler's presentation were:

- The OMII approach has been revised to strengthen the earlier document;
- Additional resources have been added and efforts increased to achieve ad

ditional

buy-in

down to the supervisory level;

- Actions are being taken to strengthen corrective actions;
- As part of developing the revised version, reviews were done against the

documents

originally intended for input to confirm that the plan, as revised, addr
esses the issues

and

the needed corrective actions;

- A cross-walk has been developed to identify the relationship between the

OMII Action

Summaries and Objectives and the original documents that identified issu
es and needed

corrective actions (including the root cause analyses);

- Clear defined schedules for implementation of actions in the OMII will b
e included as

part

of the OMII;

- Performance metrics will be an integral part of the OMII to measure both
progress in

implementation and effectiveness;

- The OMII is a Program initiative that involves representatives from each
program team

member and requires that all of the Program/Project organizations act as
a team in

carrying out the actions of the OMII.

Aspects of the DOE program and reporting on its progress and results will
be made visible

to

the project at large -- not just to managers. Responsible managers have bee
n named at

both

DOE (Mr. Ziegler) and BSC (Ms. Nancy Williams). The intent is for this to be one program

and for involved personnel to treat it as a single cooperative program. Part of the intent of the

revision is to assure that results of the root cause analysis were properly included. When done,

the outcome of OMII should be greater than the sum of its parts.

The NRC observed that the original January submittal did not meet NRC expectations as was

confirmed by a team assisting the onsite representatives in evaluating the action summaries. It

-4-

now appears (with the April 5, 2002 letter) that OMII is back on track, but the NRC is awaiting the results.

Mr. Ziegler offered that his goal was to complete the OMII by the end of April, however, Dr.

Dyer told Mr. William Reamer (RC) that the "next few months" would be reasonable, that

DOE is committed to do it right.²

Mr. Reamer asked whether a lessons learned was being done on the way the OMII was

handled earlier. Dr. Dyer confirmed that that was the case, and that he expected input within

a month.

Mr. Latta (NRC) asked how DOE would update the NRC on the status of corrective actions,

which Dr. Dyer essentially took under advisement.

Mr. Latta asked whether the OMII would include detailed schedules for implementation, to

which Mr. Ziegler replied affirmatively.

Mr. Latta asked about an audit schedule to verify the implementation of corrective actions.

Mr. Ziegler responded that the OMII will require quarterly audits with established schedules

and semi-annual management assessments.

Mr. Latta asked about whether the intent is for OMII to be a "living" document (which was alluded to in pre-revision discussions), to which Mr. Ziegler replied his expectation is that the

OMII will take DOE where it needs to go, at which time regular processes would follow. It is not expected to take on a life of its own, but will probably be ongoing for one to two years.

Mr. Wes Patrick (of the Center for Nuclear Waste Regulatory Analysis) raised a question regarding techniques for ownership and accountability. Mr. Ziegler replied that this effort had

already begun with a kick-off meeting led by senior management and attended by key middle management representatives. He also discussed the use of a core team and sub-groups. In

addition, the people getting the assignments are helping develop plans.

Mr. Patrick asked about incentives for personnel; Mr. Ziegler responded that incentives and

measurements in performance plans are, in general, contained in the Human Performance objective.

Status of Data Model, and Software Corrective Action Reports (presented by Ms. Nancy Williams, BSC Manager of Projects) - Enclosure 53

2 In subsequent discussion on the NRC/DOE Quarterly Management Meeting on April 19, 2002, John Greeves (NRC) requested that the submittal be made at least 30 days prior to the next Management Meeting.

3 It was discovered immediately following the meeting that the footnote on slide 5 has errors; the

footnote should indicate:

- "Accepted (860)" instead of "Accepted (863)"
- "Source VLI (352Y)" instead of "Source VLI (332)"
- "Total Data Citations (1212)" instead of "Total Data Citations (1195)"

5)"

-5-

The overall theme is that DOE is making changes to ensure the infusion of quality attributes

earlier in the processes (rather than later as has been the case previously). The focus is on

effectiveness and timeliness of corrective action. New modeling procedures being developed

will be consistent with the guidance in NUREG- 1636. Additionally, self-assessments will be

performed during the model development process focusing on validation, planning and execution.

Desktop guidance is being prepared to facilitate the process. The draft is scheduled for late

next week; users have been consulted in the process. Currently DOE is using a "traveler" to

implement guidance. In addition, a commercial process has been purchased to assist in the software effort.

Mr. Latta stated that he recognized all data was qualified, but asked about the status of software? Ms. Williams discussed DR-88 that had identified 4 pieces of software requiring qualification; two are now complete, the remaining two are being finalized. She indicated that

there is no impact on the TSPA-SR.

Mr. Latta asked if the project had an established plan for lifting the management stand-down

on software development. Ms. Williams responded to Mr. Latta that lifting the management stand down hinges on procedure revision and training (Procedure AP-SI. 1Q) and that the Technical Work Planning (TWP) process has been proceduralized and was in place in December (with the procedure revision).

A question was raised by a member of the public as to whether the models are available to

the public. DOE responded that the models for supporting the LA are still under development, but once completed will be available to the public.

ware models Mr. Mike Markley (NRC) asked about how quality assurance would address software and software reliability specifically with regard to common mode failures. Responding to this question will be a new action item.

where they Ms. Susan Zimmerman Lynch (state of Nevada) asked who the IT experts were, had come from and where they were assigned while on the project. It was agreed that responding to this question would be a new action item.

s: would Mr. Larry Campbell (NRC) asked about new models and internal audit schedules: would OQA audits be performance-based or compliance/programmatic-based? Ms. Williams responded that audits would likely be scheduled when sufficient work was completed to make the audits valuable (likely not sooner than another three months). Audits will encompass both compliance and performance issues using Chief Science Office staff personnel (who are independent of those who are actually conducting the work) as technical experts. Mr. Murthy

also addressed this issue and responded that OQA will continue to conduct performance and compliance-based audits, and emphasized that performance-based audits will be conducted on

The body of the slide is unchanged.

standing that OMII and CAR-related committed actions. Campbell restated his understanding that OQA

would be conducting performance based audits.

The NRC requested an audit schedule (for Analysis Model Reports) for planning purposes.

DOE expects audit schedules to be available based on the results of the OMI I and LA planning.

Ms. Williams stated that DOE would revisit the qualification processes for data used for LA.

Metal Specimens Issues (presented by Dr. Mark Peters BSC Manager, Science and Engineering Testing) - Enclosure 6

The Metal Specimens issue involves incorrect fabrication of test specimens intended for use

in corrosion testing and loss of traceability of material provided to the supplier to be used

during the fabrication. This problem resulted in four Deficiency Reports (three of which are

closed) and one Corrective Action Report (now closed). The corrective actions include

removing the supplier from the Qualified Supplier List, increased attention to supplier

quality (including improvements in clarity of communication to suppliers), development of

materials/samples acceptance plans, and establishment of hold points during the

fabrication process.

At the conclusion of the presentation, a question was raised regarding whether a lessons

learned had been conducted on these issues. The response is that a lessons learned has

not been done at this time, but is scheduled in conjunction with a scheduled June 2002 self-

assessment. Another question regarded what the samples were used for if they did not

impact the SR (as was stated in the presentation). The samples were to be used to support

planned LA work. Another NRC question was whether the situation would impact satisfactory

completion of the KTI Agreement Items. Dr. Peters responded that they will not have an

impact; this
schedule issue has already been considered.

The Center asked if these were the 1 - 1/2" square corrosion samples numbered D- 1 through D-

75. It was agreed that providing a response to this question would be an action item from the meeting.

Action Items (presented by Ms. April Gil, DOE)

This covered the status of action items from the last meeting and identified new actions from

this meeting. The action items and their status are shown on Enclosure 7.
Closing Remarks

The NRC commented in closing that this meeting is not the end point of the resolution but may mark beginning of resolution. Dr. Chu commented that she expected the upcoming

-7-

period to be challenging and that she is expecting steady improvement. Dr. Dyer indicated

that the proof will be in DOE performance on YMP.

The NRC invited members of the public to provide comments via the Public Meeting

Comment Forms which were available. ; ; 1/4 ; --date 1/4 ~ o ~

~ date 1/4 ~ Jd ~

anet Schleuter, Branch Chief '7 Ra~Murthy, Acting Director
Division of Waste Management Office of Quality Assurance
Office of Nuclear Material Office of Civilian Radioactive
Safety and Safeguards Waste Management
U.S. Nuclear Regulatory Commission U.S. Department of Energy

ate _____

J eph Ziegi , A ting AMOLRC
Office of Licensing and
Regulatory Compliance
Yucca Mountain Site

29.ocr

Characterization Office
U.S. Department of Energy

-8-

List of Enclosures
For
April 18, 2002
QA Meeting Summary

Enclosure Description

- 1 Agenda
- 2 Affendance List
- 3 Quality Assurance Program Status
- 4 OCRWM Management Improvement Initiatives
- 5 Status of Data, Model and Software Corrective Action Reports
- 6 Metal Specimens Issues
- 7 Action Items

ENCLOSURE I

Agenda
DOE/NRC Quarterly QA Meeting
April 18, 2002
9:00 AM - 12:00 PM (PT)
12:00 Noon - 3:00 PM (ET)

BSC
Room 915
Page 13

And via Videoconference to:

U.S. Department of Energy	U.S. Nuclear Regulatory Commission
Forrestal Building, Room 7F-091	Room O-3B4
1000 Independence Avenue, SW	11545 Rockville Pike
Washington, DC 20585	Rockville, MD

9:00 AM	Introduction	
	• Opening Remarks	DOE/NRC
9:20 AM	QA Program	Mu rthv
	• QA Organization	
	• Status of Open CARs and DRs	
	• Trending Results	
	• Other Emerging Issues	
	• QARD Status	

10:20 AM	Model and Software CARs	N. Williams
	<ul style="list-style-type: none"> • Steps to Prevent Recurrence • Status of Data and Software Qualification • Model Validation 	
10:50	OQA Oversight of CARs and OMII	Murthy
11:00	Break	ALL
11:15AM	Metal Sample Supplier QA Issues	Peters
11:30PM	Action Item Status	Gil
11:45 PM	Closing Remarks	ALL
12:00N	Adjourn	

QA: N/A

DOE - NRC Quarterly Quality Assurance Meeting
Las Vegas, NV
April 18, 2002

~
 ~
 4~ ~lL~?
 ~
 ~
 'f(~ \$~(§~f~ ~¼S77~
 ~ JLj~))~ (4.~ 10~ ~ Yo~#~
 F\\#~~~ ~(M~~[£c & 2G~~37. /' /~~
 ~
 ~
 ~7z ~ ~iTh
 ~£//A/{ /(,~ ~ ./-- 37~7~£
 J'~Z/ /¼~/// ~ c/~

29.ocr

~i7, C~~f&~~O ~ 7ci y
7o t

pJ~
I

QA: N/A

ATTENDANCE LIST

DOE - NRC Quarterly Quality Assurance Meeting
Las Vegas, NV
April18, 2002

Name	t	Organization	Telephone
½\$½ffi~~ ~			~? 79~ ~
~,)~			&2) ~

Th~ ~

\~\'~ \\\

'½ 1/	~i¼	~2 7~~x'//y
~tl ~		~

~

QA: NIA

ATTENDANCE LIST

DOE - NRC Quarterly Quality Assurance Meeting
Las Vegas, NV
April18, 2002

Name	T	Organization	Telephone
------	---	--------------	-----------

QA: N~A

ATTENDANCE LIST

DOE - NRC Quarterly Quality Assurance Meeting
Las Vegas, NV
April18, 2002

Name	j	Organization	Telephone	J
------	---	--------------	-----------	---

~. \$u(?~~~1 ~o~- O~A

~ ~
~ •ftL~AJ ~()(-~~ ~
~PR-1e~~2 12 ~2 kkU~~~ ~ .

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

29.ocr
MEETING ATTENDANCE
ORGANIZATION

TITLEIFUNCTION TELEPHONE NUMB

ER

~	I,	•Te~~ ~	
~ ~			-J~o
~ ~£455&~~	C~A,WI~	ki,~ ~	
	cAi~~		
		~ ~	~2Z ~

CNWRA Ferm AP-5

DOE/NRC QA Meeting
April 18, 2002 DOE HQ

ORGAMZATION TELE~HONE
~',~)-f~ ~
- ~
(:~o~5~ce- ~

~
~AA1 ~I ~ ~A ~-

~~40f7 ~

L rL ~

p e-1~

~ -~g~

p

T~d 101

AJTENDA~CE LIST
NRC/DOE QUARTERLY QUALI~ ASSURANCE MEETING
ROCKVILLE, MD
APRIL 18, 2002

Name	Organization	TelBphone
~	&)A5~~	~ VA ~ -6~7
~	J~ ,7hr ~	~ ~15~ ~
	~	~ ~
	~'	~
	~	~J ~

~ 'd

~£:9T ~

ENCLOSURE 3

YUCCA MOUNTAIN PROJECT

(~ U.S. Department of Lflerg\
Office of Civitian Radioactive Waste Management
7

•~ LF~Cf;j~~ h~LL.~~\:::F/ :~'~ ~ ~LL~ L~ ZU½\~ FF: (; ; ~. F. : ; DF~) 7!~Q%\$
I) ;7>~3j.
L~g~:D ~<>qj ~t::~ b., i ; ~ ; ; ; - F) ; --7:~

Presented to:
DOEINRC Quarterly Quality Assurance Meeting

Presented by:
Ram Murthy
Acting Director, Office of Quality Assurance..
Office of Civilian Radioactive Wa~e Management
Yucca Mountain Site Charactelr~ation Office
Outline

- QA Organization Status
- Corrective Action Report (CAR) Status
- Trending ResultslEmerging Issues
- QARD Revisions
- Summary

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOEINRC Qua

rterly

QA~YMMurthy1~04I18IO2 ppt 2

QA Organization Status

- The Department of Energy (DOE), as the potential licensee, is responsible for the OCRWM QA functions

29.ocr

including the establishment and maintenance of the
QA Program and verification of program
implementation, as specified in 10 CFR Part 63.142

- DOE may delegate authority but not responsibility

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOE/NRC Qua

terly

QA~YMMurthy1~04I18/02 ppt 3

QA Organization Status
(Continued)

- DOE Office of Quality Assurance (DOE OQA) and Bechtel SAIC Company, LLC (BSC QA) perform QA activities. Each organization has unique roles and responsibilities
- DOE OQA is responsible for oversight of all Affected Organizations performing work in accordance with the OCRWM QARD

YUCCA MOUNTAIN PROJECT

BSC P~sentations_DOE/NRC Quar

terly

QA~YMMurthy1~04/18IO2 ppt 4

QA Organization Status
(Continued)

- The BSC contract was recently modified to include the performance of internal audits and surveillance of BSC activities; including vendors, the USGS, and National Laboratories that support the BSC work scope

29.ocr

- BSC QA currently performs surveillance of BSC activities
- DOE OQA will observe selected BSC QA surveillance and in the future will observe BSC audits

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOEINRC Qu

arterly

QA~YMMurthy1~04/18IO2 ppt 5

Corrective Action Report (CAR) Status

- Modeling CAR (BSC-01-C-001) - Response accepted
- Software CAR (BSC-01-C-002) -Awaiting amended response
- Training CAR (BSC-02-C-001) - Response accepted and will be in OQA verification by the end of April 2002
- Metal Samples CAR (BSC(V)-02-C-002) - closed April 4, 2002

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOE/NRC Qua

rterly

QA~YMMurthy1~04/18IO2 ppt 6

Trending ResultsEmerging Issues (July 1, 2001 - December31, 2001)

- The OCRWM Trend Report (Second Semester 2001) identified two emerging issues
- Supplier Deficiencies
 - Similar conditions identified at several BSC suppliers in several program areas; e.g., Training, Procurement Document Control, Control of M&TE, Audits, etc.
 - Not a repeat condition at one supplier
 - BSC has taken prompt management action
 - OQA will verify effective implementation of actions taken

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOE/NRC Qu

arterly

QA~YMMurthy1~04/18/02 ppt 7

Trending ResultsEmerging Issues
(July 1, 2001 - December31, 2001)
(Continued)

- Cause Code - Personnel Error (Inattention to Detail)
 - Personnel errors due to inattention to detail have been increasing; however:
 - Individually, these conditions are not significant
 - Majority are compliance type. No impact on products
 - Trend is notice of early concern
 - DOE and BSC Senior Management has initiated management actions
 - OQA will monitor this cause code quarterly to evaluate trend

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOEINRC Qua

rterly

QA~YMMurthy1~04118/02 ppt 8

OCRWM QARD Revisions

- Revision 11 strengthened requirements for model validation utilizing NUREG-1636 as the basis document
- Revision 12 will address QA organizational changes
- Revision 13 will address new Yucca Mountain Review Plan

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOE/NRC Qua

rterly

QA~YMMurthy1~04I18/02 ppt 9

Summary

- QA organization changes will ensure that the effectiveness of the QA program is enhanced
- QA trending has resulted in the early identification of emerging issues and management actions were taken
- QARD Revision 11 is approved

YUCCA MOUNTAIN PROJECT

BSC Presentations_DOE/NRC Qua

rterly

QA~YMMurthy1~04/1 8102 ppt 10

ENCLOSURE 4

~I~jIj~

~~~~~.~~~~~.~~~~~ ~-

----~ YUCCA MOUNTAIN  
PROJECT

U.S. Department of~Lnergy  
Office of Civilian Radioactive ~'aste Management  
-- -- -- (I

j\~j ~  
-- - 'I ~ -  
1/4 ~ ~ ~ hH 1/2;A~1/2!~1/2j:l  
1/24/4 ~ -j r>l ~  
~ F ~ .~ThpThlQ>[>~. ~ L~ L\$4~ ;\] L~1] 7' ;;;~ ~ ; -1/4;

\!; (,2~

] ~  
UL -- HHH~r=jHL - --.---

Presented to:  
DOEINRC Quarterly Quality Assurance Meeting

Presented by:  
Joseph Ziegler  
DOE Senior Technical Advisor  
Office of Civilian Radioactive W~e Management  
Yucca Mountain Site Character~ation Office

- - - -

Ap~iI 18,

k~sYega~5

Objective

- Present the revised approach and restructuring of the OCRWM Management Improvement Initiative (OMII)
- Reiterate Management commitment and involvement in the OMII development and implementation
- Present mechanism for tracking and communicating results of OMII implementation

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rterly

QA~YMZiegIeL04/18/02 ppt 2

Revised Approach - OMII

- Re-evaluate OMII to strengthen the approach and ensure effective actions to prevent recurrence
- Develop and incorporate lessons learned from previous corrective actions and management initiatives
- More comprehensive to include clearly defined actions, schedules and metrics
- Reissue as ~ document and implement in accordance with AP-5.IQ, Plan and Procedure Preparation, Review and Approval

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rterly

QA~YMZiegler~04/1 8/02 ppt 3

Revised Approach - OMII  
(Continued)

- Require assessment of completion and effectiveness by responsible managers, DOE & BSC QA, and senior management

Implement management tool to track and  
communicate results to project staff

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rtterly

QA~YMZiegler~04/18IO2 ppt 4

Management Commitment

- DOE senior manager assigned full-time responsibility for developing the revised OMII
- Executive leadership team will monitor performance on a weekly basis
- Director of OCRWM will track progress on a weekly basis

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rtterly

QA~YMZiegler~04/18/02 ppt 5

Management Commitment  
(Continued)

- Joint DOEIBSC (including National Labs and USGS) leadership for initiatives
  - Development of action summaries including:
    - Remedial actions and actions to preclude recurrence for the Model and Software CARs
    - Other planned actions not directly part of CAR corrective actions, but within NRC regulatory purview and subject to DOE QARD
    - Additional improvements from project business practices that are appropriate to support overall performance



29.ocr

- Overall effectiveness reviews after implementation
- Ownership and accountability of results
- Integration sessions to achieve alignment on actions, problems, causes and path forward
- Firm commitment by management from all program participants to ensure buy-in and ownership~ of all actions

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

Quarterly QA~YMZieglerL04/1

8/02 ppt 6

Model Software CARs and OMII Interface

- Considers management actions necessary to specifically address lack of timely identification of actions to preclude recurrence of conditions adverse to quality
- Parallel information in CARs and OMII
- CAR focus
  - corrective actions to address specific deficiencies
  - corrective actions to address causes and recommendations
  - Performance measures for progress and effectiveness

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

Quarterly

QA~YMziegler~04I18/02 ppt 7

Model Software CARs and OMII Interface

(Continued)

OMI focus

- Corrective actions related to management functions, such as human performance and project management, in addition to quality issues
- Performance measures for progress and effectiveness
- Detailed action summaries
- Overall achievement of plan objectives

YU

CCA MOUNTAIN PROJ~CT

BSC Presentations\_DOE/NRC Quarter

ly

QA~YMZiegIeL04I18/O2 ppt 8

## Concluding Remarks

- Dedicated DOE Senior Management assigned for OMII planning activities
- DOE & BSC (including National Labs and USGS) Management team commitment and ownership of implementation
- Comprehensive incorporation of lessons learned, management initiatives and CAR Corrective Action Plans
- Actions, schedules, results, and performance metrics tracked and communicated to internal and external organizations

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOEINRC Qua

rterly

QA~YMZiegIe~04I1aIo2 ppt 9

ENCLOSURE 5

-

Uj~~epatrnt of Bnergy

-

YUCCA MOUNTAIN

PROJECT

Office of Civilian Radioactive Waste Mana~emenl

(¼ Th~- \_\_\_\_ (1 A ¼ ½~L

7 (¼

I-I )~½1I I ¼~~i(½<¼ \_\_\_\_  
 I 7¼- 7 i~5~

(I

F-- El

Ii \_ (f~II (f¼\ 7 I7~~~«¼ ½)

I Ii ½½

ffi 1½

\_\_\_\_ 1/

½¼~¼

&lt;7&lt; ; )

II

Presented to:

DOEINRC Quarterly Quality Assurance Meeting

Presented by:

Nancy Williams

Manager of Projects

- - -

A~j~~iI18,2p02~ ~

Objective

- Provide overview of data strategy and planning for License Application (LA)
- Provide status of CAR actions taken since March 2002

---

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qu

arterly

QA~YMWiIiams~04/18/02 ppt 2

Scientific Data Status

- All data for Site Recommendation Qualified andlor Verified
- Developing plans and processes to manage data needs for LA
  - Identifying qualification needs for data to support LA Design and Total System Performance Assessment (TSPA) updates
  - Developing approach for
    - Ensuring defensibility of data used in LA
    - Dispositioning unusedlunneeded data
- Will keep NRC apprised of progress

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qu

arterly

QA\_YMWiIIiams~04118/02 ppt 3

## TSPA-SR PMR Data Status

|                  | % Data<br>Qualified | % Data<br>Verified |
|------------------|---------------------|--------------------|
| PMR              |                     |                    |
| Biosphere        | 100                 | 100                |
| DisruptiveEvents | 100                 | 100                |
| EBS              | 100                 | 100                |
| ISM              | 100                 | 100                |
| Near Field       | 100                 | 100                |
| SZ F&T           | 100                 | 100                |
| UZ F&T           | 100                 | 100                |
| Waste Form       | 100                 | 100                |
| Waste Package    | 100                 | 100                |
| Total            | 100                 | 100                |

Data status as of 04/15/2002

Percent completion for data figures are based upon Data Tracking Numbers co  
ntained in  
locked

Document Input Reference System for TSPA-SR Rev 0, ICN 1.

YUCCA MOUNT

AIN PROJECT

BSc Presentations\_DOEINRC Quarterly QA~YMW

iilliams~04118IO2

ppt 4

## VerificationQual ification Status-TS PA-SR 04115102

|                                  | Total | Completed | To-Go |             |
|----------------------------------|-------|-----------|-------|-------------|
| VL1 DIRS (Venf. Checklists)      | 250   | 250       | 0     | (Q-TBV) ("a |
| ctual citations")                |       |           |       |             |
| VL1 Sources (Verif. Checklists)  | 352   | 352       | 0     | (Q-TBV) ("d |
| aughters")                       |       |           |       |             |
| VL2 (No Verification Checklists) | 182   | 182       | 0     | (Q-TBV)     |
| Accepted Data (Fact)             | 78    | 78        | 0     | (e.g., hand |
| books, textbooks)                |       |           |       |             |
| Accepted Data approved by        | 32    | 32        | 0     | (e.g., non- |
| project source)                  |       |           |       |             |
| Assistant Manager, Office of     |       |           |       |             |
| Project Execution                |       |           |       |             |
| Qualified by procedures          | 36    | 36        | 0     |             |
| established after 6130199        |       |           |       |             |
| Unqualified DTNS qualified       | 282   | 282       | 0     |             |
| per AP-SIII.2Q                   |       |           |       |             |
| Totals                           | 1212  | 1212      | 0     |             |
| Percent of Total Data Citations  |       | 100%      | 0%    |             |

Notes: Document Input Reference System VL1+VL2+AP-SIII.2Q+Accepted (863)

+

29.ocr

Source VL1 (332) = Total Data Citations (1195)

VL1 = Principal Factor Related DTN      VL2 = Non-Principal Factor Related DTN

Percent completion for data figures are based upon Data Tracking Numbers contained in locked Document~

Input Reference System for TSPA-SR Rev 0, ICN 1.

Y

UCCA MOUNTAIN PROJECT

BSc Presentations\_DOE/NRC Quarterly

erly

QA\_YMWIIIiams~04/18/02 ppt      5

Models Validation Status

Model Validation Corrective Action Report (CAR)  
(BSC-01 -C-001)

- Corrective Actions to Prevent Recurrence (CATPR) essentially complete
- CATPR re-evaluated and expanded slightly to ensure root causes adequately addressed; Actions in progress
- Remedial actions will be applied to models carried forward to LA; Model planning and development in progress

---

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Quarterly

arterly

QA\_YMWIIIiams~04/18/02 ppt      6

Status of Model Validation  
Corrective Actions

- corrective Actions completed include:
  - chief Science Office assigned functional management responsibility
  - complete revision of AMR procedure into 2 new procedures
    - AP-SIII.IOQ - Models
    - AP-SIII.9Q - Scientific Analyses
  - Training on new modeling procedure by cso subject matter expert completed by 1212112001
  - Training included testing on information presented
  - Model workshop conducted during training session
  - Line and Functional Management involved in training sessions

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rtterly

QA~YMWiIIiams~04/18/02 ppt 7

Model Validation Corrective Actions

What's Different

- Model validation is integral part of model development
  - Begins at model conception, not as a final action following mode

1

development I documentation

- Technical Work Plan defines validation approach and criteria to ensure plans for model validation are appropriate
- "Plan the work I Work the plan" concept

Chief Science Office assigned functional management responsibility

- Validation interpretive authority and procedure owner (subject matter expert)
- Reviews model validation plan (pre-AMR development or revision), draft and final model validation documentation as developed by the line organization

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOEINRC Qua

rtterly

QA\_YMWiIIiams~04/18IO2 ppt 8

Model Validation Corrective Actions

What's Different

(Continued)

- Timely self-identification of validation issues from cSo reviews allows Line Management to focus resources
- New modeling procedure developed consistent with NUREG 1636
- Self-assessments to be performed of model development process, focusing on validation planning and execution

YUCCA MOUNTAIN PROJECT

rterly

QA\_YMWIIIiams~04/1 8102 ppt 9

## Software CAR Status

- Software Quality Assurance CAR (BSC-01 -C-002)
- Remedial actions complete
- CATPR reviewed and partially accepted with OQA comments; action plan rework underway
- CATPRinprogress
  - Software submits with users and developers
  - External expertise retained
  - New procedures in development
  - Improved tools for software configuration management process being implemented
  - Interim controls from Software Stand-down enhanced

---

 YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qu

arterly

QA\_YMWIIIiams~04118/02 ppt 10

## Summary

- Data Verification and Qualification
  - Data required to support TSPA-SR, Rev 0, ICN 01 was completed to support SR
  - Planning underway to ensure that data required to support LA meets QARD data qualification requirements

Software and Model Validation CAR Preventive  
Action implementation in progress

- Revising CAR and OMII actions plans
- Under Line Management Review
- Obtaining OQA Approval
- Continuing Implementation
- NoimpacttoSR

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rterly

QA\_YMWIIIiams~04/1 8/02 ppt 11

1/2 TO~

YUCCA MOUNTAIN PROJECT

Office of Civilian Radioactive Waste Management  
 )~I~Li;1/2>jj,>Y»>7Ki Depal4rntent 77 ~ThTh  
 (1/2Th1/2L;F.1/2 :;F:~.~.

~1/2Th1/2

F>

—

F

F F

—

IF — I~ 11 1/2\> ~1/2F 1/2 (~)FF F;

Presented to:

DOEINRC Quarterly Quality Assurance Meeting

Presented by:

Ram Murthy

Acting Director, Office of Quality Assurance

Office of Civilian Radioactive Waste Management

Yucca Mountain Site Characterization Office

April 18, 2002

Las Vegas, Nevada

f

# ..

~;

# OCRWM Management Improvement Initiative (OMII) Oversight

- Office of Quality Assurance (OQA) will develop a verification schedule to perform oversight of completed actions including both "Q" and "Non-Q" activities
- OQA will conduct selective oversight activities on a phased approach through the use of audits, surveillance, and in-process verifications
- BSC QA will also perform in-process surveillance
- The schedule will be monitored by OQA and updated



on a quarterly basis

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rtterly

QA~YMMurthy2~04/1 8102 ppt 2

Corrective Action Report (CAR) Oversight

- Software
  - Identify commitments
  - Establish matrix of commitments and completion dates
  - Schedule in-process verification
  - Schedule verification of completed corrective action
- Modeling
  - Identify models and validation dates from P-3 Schedule
  - OQA perform verification to ensure product acceptability and process effectiveness

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rtterly

QA~YMMurthy2~04I18/02 ppt 3

ENCLOSURE 6

rTh~/T~\_\_\_\_\_

~~)~U.s;Department of L1/gy

Oft~ce o~ Civilian Radioactive \Vaste Managejit -

YUCCA MOUNTAIN  
PROJECT

L

Presented to:

DOEINRC Quarterly Quality Assurance Meeting

Presented by:

Mark Peters

Manager, Science and Engineering Testing

Bechtel SAIC Company, LLCIL~Iamos Na~tional Laboratory

L~s~ V

<~

ii;

Historical Perspective

- Problems

- McDermott Technologies, Inc. (MTI) had an un-tested welded specimen lightly etched to look for features of weld defects. MTI found that the specimen consisted of both weld and base metal. This specimen was to be composed entirely of weld metal
- This prompted an investigation into the placement of welds for all customer supplied welded Alloy 22 and TiGr7 specimens, fabricated by a supplier on the OCRWM Quality Supplier List (QSL), at Lawrence Livermore National Laboratory (LLNL) and MTI

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOEINRC Qua

rtterly

MM\_YMPeters\_04/19/02 ppt 2

Historical Perspective  
(Continued)

- Evaluations at LLNL and MTI revealed that specimens were not fabricated in accordance with the specimen sampling location drawings and sketches included with purchase orders awarded to the supplier
- Investigations performed by Science and Engineering Testing (S&ET) further revealed that a combination of poor planning, lack of communication, and lack of direction by the technical organization contributed to this problem
- Documented in deficiency report BSC(V)-01-D-124 - Closed on December 12, 2001

YUCCA

MOUNTAIN PROJECT

BSC Presentations\_DOEINRC Quarterly

MM\_YMPeters\_04/19/02

ppt 3

Historical Perspective  
(Continued)

- During MTI's evaluations of the misplacement of welds, MTI reported 2 specimens as having a notch located in the incorrect location. This prompted the S&ET organization along with BSC QA to observe the supplier's process (at their facility) for fabricating specimens. The outcome of that visit indicated a loss of traceability of customer supplied Alloy 22 and TiGr7 welded plate at receipt at the supplier's facility
- The supplier failed to record customer supplied Alloy 22 and TiGr7 welded plate shipped from Framatome Technologies, Inc. to MSC for fabricating test specimens
- Documented in corrective action report BSC(V)-02-C-002 - status provided below

Root cause Analysis Completed

YUCCA

MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Quarterly

MM\_YMPeters\_04119102 ppt 4

Historical Perspective  
(Continued)

- Corrective Actions Taken
  - The supplier has been removed from the OCRWM QSL
  - Reassignment of roles and responsibilities in S&ET
  - BSC QA implementing processes to improve supplier quality (communication, surveillances, follow-up audits)
  - S&ET, BSC QA, and Procurement working together to provide clear and concise direction in supplier contracts and analytical technical service contracts
    - Transfer of material between suppliers and across organizations
    - Development of material sample acceptance plans
    - Hold points during fabrication process

YUCCA MOUNTAIN PROJECT

rterly

MM\_YMPeters\_04/19/02 ppt 5

## Status of Conditions Adverse to Quality

- CAR No. BSC(V)-02-C-002 (Loss of Traceability)
  - Closed April 4, 2002
  - Material to be controlled by NCRs
- Outstanding Deficiency Reports
  - BSC(V)-02-D-043, supplier deficient in calibrating roughness standards. The standards have since been calibrated to a master standard and found to be in tolerance. DR is closed (no impact to YMP work)
  - BSC(V)-02-D-044, supplier failed to complete an anomaly report for specimens that were out of tolerance. The specimens are being used for non-Q testing activities. DR is closed (no impact to YMP work)

## YUCCA MOUNTAIN PROJECT

rterly

MM\_YMPeters\_04/19/02 ppt 6

Status of Conditions Adverse to Quality  
(Continued)

- BSC(V)-02-D-045, supplier is deficient in evaluating sub-tier suppliers. One outstanding supplier (R&R Gage Co.) still needs to be evaluated. (Evaluation of impact is ongoing)

YUC

## CA MOUNTAIN PROJECT

29.ocr

Y

MM\_YMPeters\_04/1~/02 ppt 7

#### Non-Conformance Reports

- Two NCRs (YMSCO-02-0021 Loss of Traceability and YMSCO-01 -0035 Misplacement of Welds) were generated to control specimens
  - Affected specimens at LLNL and MTI segregated and red-tagged
    - Samples will not be used for any further testing

#### YUCCA MOUNTAIN PROJECT

BSC Pfesentations\_DOE/NRC Qua

rterly

MM\_YMPeters\_04/19/02 ppt 8

#### Impact

- No Impact to SR products
- Impact to LA products
  - Sufficient samples will be in test to support LA-CA

#### YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rterly

MM\_YMPeters\_04/19/02 ppt 9

#### Path Forward

Laboratory Testing, Inc. (LTI) to Fabricate Replacement Specimens and Remainder of FY02

Specimens

- BSC QA audited LTI December 2001 with emphasis on traceability of customer supplied material - no findings
- Hold points included in the list of items to LTI's statement of work
- Surveillance by BSC QA of the fabrication process at LTI's facility scheduled for April 23, 2002

S&ET Currently Evaluating Future Specimen Needs

- Contract will be awarded through competitive bid process

YUCCA

MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Quarterly

MM\_YMPeters\_04/19/02 ppt 10

Path Forward

(Continued)

- Self Assessment

- Target Completion Date is June 30, 2002

YUCCA MOUNTAIN PROJECT

BSC Presentations\_DOE/NRC Qua

rterly

MM~YMPeters\_04/19/02 ppt 11

ENCLOSURE 7

Combined Action Items

From The

December 5, 2001 And The April 18, 2002

NRC/DOE Quarterly QA Meeting

Item No.

Description

Status

copy of 5Dec01-1 DOE will provide to NRC the project responses to the QAMA recommendations the project responses to the QAMA recommendations by letter dated April 15, 2002 Completed: DOE provided a

f 5Dec01 -2 DOE will provide follow-up information/status to NRC on 2002 Quarterly QA Meeting in lieu o deficiencies related to metal samples. an Appendix 7 meeting. This will be accomplished via an Appendix 7 meetin~ if appropriate. Completed: was discussed in April

s 5Dec01-3 DOE will request the QAMA team to Open: the FY 2002 QAMA Plan wa include evaluation of the DOE/BSC issued on March 11,2002 without performance measures/metrics in the specific provision for in cluding scope of their FY 2002 assessment. performance measures in t he evaluation. A revised scope will be issued\_to\_cover\_this\_item.

d action with 5Dec01-4 Director, OQA, will follow-up with Clark County, NV, regarding Clark County, NV per email on 1/2/0 2. information that some labs are not Closure with the State of Nevada was documenting all problems. The State completed (also by email) on February of Nevada will also be informed of 12, 2002. the outcome.

RC was 5Dec01-5 DOE agreed to inform NRC of any changes in OQA/BSC QA responsibilities prior to their implementation. Open: on March 19, 2002, the N informed by letter of the first step in changing QA responsibilities: BSC's assumption of internal surveillances and internal corrective action activities (with some limitations). These changes were effective on March 25, 2002. It is anticipated that this action item will be completed with the issuance of QARD Rev. 12 prior to implementing further changes; however, if such changes are implemented prior to issuance of Rev. 12, the NRC will be informed prior to implementation.

em

the external (independent) software  
experts, where they are from and  
where they are assigned on the  
\_\_\_\_\_ project. \_\_\_\_\_

Page 1 of 2

Combined Action Items

From The

December 5, 2001 And The April 18, 2002

NRC/DOE Quarterly QA Meeting

1 8Apr02-2

Respond to Mike Markeley ~RC) New Action

Item

question on QA and the potential for  
software cornrnnon mode failures.

1 8Apr02-3

Confirm with regard to the "metal New A

ction Item

specimens" issue that the  
sample/plates being discussed were  
the 1 V2 in. plates intended for  
corrosion testing with serial numbers  
D-1 through D-77 and that all

samples were red-tagged.

1 8Apr02-4

DOE will provide the NRC with an New A

ction Item

audit schedule (to enable the NRC to  
facilitate their planning) for Analysis

Model Reports when available.



29.ocr

Page2of2